REMARKS

The Remarks presented November 20, 2003 in response to the final Office Action and Advisory Action are being resubmitted herein.

Claims 2, 3, 8-10, 19 and 20 remain in this application. Claims 1 and 11 have previously been canceled. Claims 4-7 and 12-18 are canceled herein.

In view of the Office's earlier restriction requirement, Applicants retain the right to present claims 4-7 and 12-18 in a divisional application

I. THE NOVEMBER 19, 2003 TELEPHONIC INTERVIEW

Applicants thank the Examiner and her supervisor for the courtesy extended during the November 19, 2003 telephonic interview. The substance of the interview is incorporated in the following remarks.

II. THE WITHDRAWAL OF THE OBJECTION TO CLAIM 8

Applicants acknowledge the Advisory Action's withdrawal of the objection to claim 8.

III. THE REJECTION OF CLAIM 8 UNDER 35 U.S.C. § 101

The Advisory Action rejects claim 8 under 35 U.S.C. § 101 asserting that the proposed amendment, which changes "the DNA of claim 2" to "A nucleic acid" and then goes on to specify that the nucleic acid comprises SEQ ID NO: 1 raises a new issue that would require further consideration under 35 U.S.C. § 101. Applicants respectfully traverse the rejection.

Applicants respectfully submit that the amendment to claim 8 does not add any "new" issues under 37 U.S.C. § 101, and rather merely placed previously written claim 8 in independent form. For clarity, Applicants amend claim 8 herein to specify that the nucleic acid is "isolated". Reconsideration and withdrawal of the rejection of claim 8 under 35 U.S.C. § 101 are respectfully requested.

IV. THE REJECTIONS UNDER 35 U.S.C. § 101
AND 35 U.S.C. § 112, FIRST PARAGRAPH

The Advisory Action maintains the rejection of claims 2, 3, 8-10, 19 and 20 under 35 U.S.C. § 101 as lacking utility. The Advisory Action also maintains the rejection of claims 2, 3, 8-10, 19 and 20 under 35 U.S.C. § 112, first paragraph. In particular, the Advisory Action asserts that "the present application does not disclose any specific and/or substantial utility directly associated with the claimed nucleic acid. Further, even if the post filing art . . . established that the presently claimed nucleic acid had a specific and substantial utility . . . it cannot be used to support the asserted utility in the present invention because such use is not disclosed in the instant specification." Applicants respectfully traverse the rejections.

Applicants respectfully submit that the asserted utility and the disclosure of the present specification meet the utility requirements of 35 U.S.C. § 101. As set forth in the Manual of Patent Examining Procedures ("MPEP"):

> An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible . . .
>
> If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a "specific and substantial utility") and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility.

MPEP 2107 II(A)(1)(3) and (B)(1) (emphasis added).

> Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement.

MPEP 2107(D).

> As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility. *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980). An applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in scientific journals), or any combination thereof. The applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted. Instead, as the courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use. *Nelson v. Bowler*, 626 F.2d 853, 857, 206 USPQ 881, 884 (CCPA 1980).

MPEP 2107.03 I.

> Courts have routinely found evidence of structural similarity to a compound known to have a particular therapeutic or pharmacological utility as being supportive of an assertion of therapeutic utility for a new compound. In *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980), the claimed compounds were found to have utility based on a finding of a close structural relationship to daunorubicin and doxorubicin and shared pharmacological activity with those compounds, both of which were known to be useful in cancer chemotherapy. The evidence of close structural similarity with the known compounds was presented in conjunction with evidence demonstrating substantial activity of the claimed compounds in animals customarily employed for screening anticancer agents. Such evidence should be given appropriate weight in determining whether one skilled in the art would find the asserted utility credible. Office personnel should evaluate not only the existence of the structural relationship, but also the reasoning used by the applicant or a declarant to explain why that structural similarity is believed to be relevant to the applicant"s assertion of utility.

MPEP 2107.03 II.

Applicants' asserted utility and disclosure meet the guidelines provided in the MPEP. As Applicants pointed out in the Amendment filed on August 20, 2003 ("Amendment"), the specification at page 10 specifically discloses a utility for the claimed invention, namely "that α10 contributes to cholinergic transmission both in the CNS and in certain non-neuronal tissues with importance to the hormonal and immunological status of the organism." This asserted utility is exemplified in the Examples at pages 48-55 of the specification. For example, the specification discloses (1) that α10 has a region of homology to α9, a previously known and studied protein; (2) that ion channel function of α10 was studied; and (3) that nAchR function and pharmacology was studied. Applicants respectfully submit that the specification as filed provides ample support for the asserted utility.

Moreover, as discussed in the Amendment, even if the exact function of the α10 subunit was unknown, the function of nicotinic acetylcholinergic receptors in general was known as of the filing date of the present application. See, for example, the excerpt from The Encyclopedia of Molecular Biology © 1994 attached to the Amendment, which demonstrates that prior to the effective filing date of the instant application, nicotinic acetylcholine receptors "are members of the LIGAND-GATED ION CHANNEL SUPERFAMILY" and then goes on to discuss the function of the receptors. Thus, one of skill in the art would readily have recognized the utility of studying any identified subunit of the receptor as of the effective filing date. Moreover, the articles submitted by Applicants on August 20, 2003, provide further support that Applicants' asserted utility was not futile. During the telephonic interview, the Examiner and her supervisor expressed their belief that even though the present specification disclosed a

biological activity for the claimed polypeptide, such activity did not translate to a utility. The Examiner and her supervisor indicated, however, that applicants may be able to demonstrate such utility if applicants could tie the biological activity to a readily available use, a use of which was know as of the filing date. In response, the specification discloses that as of the filing date:

(1) there had been considerable interest in the AChR (see, e.g., page 2);

(2) the cloning of various family members of the AChR had been conducted (see, e.g., pages 2-3);

(3) the α9 subunit had been characterized (see pages 2-3); and

(4) patent applications for the various subunits, including the α9 subunit (i.e., WO 96/03504), had been filed (see pages 2-3).

Applicants attach herewith WO 96/03504 and three U.S. patents, i.e., U.S. Patent No. 5,683,912; 6,013,766; and 6,100,046, all of which relate to WO 96/03504. The three U.S. patents issued prior to September 14, 2000, the filing date of the present application. The patents disclose the role of nicotinic acetylcholine receptors in the art. (See, for example, cols. 1 and 2). The three patents disclose specifically that "a need exists for identifying additional members of the nicotinic acetylcholine receptor superfamily, and characterizing such nAChR subunits, as well as functional receptors assembled therefrom..." (See, e.g., U.S. Patent No. 5,683,912 at col. 2, lines 48-59). Applicants respectfully submit that one skilled in the art reading the specification, WO 96/03504 and the three patents would readily appreciate the utility of the claimed invention. Reconsideration and withdrawal of the rejections under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, are respectfully requested.

V. THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Advisory Action maintains the rejection of claim 20 under 35 U.S.C. § 112, second paragraph. In particular, the Advisory Action maintains that claim 20 is indefinite in that it is "unclear how both ('a pair') of the nucleic acid molecules from the same polypeptide (SEQ ID NO:1) are capable of directing the amplification of SEQ ID NO:1 in a PCR." Applicants respectfully traverse the rejection.

Applicants amend claim 20 herein. Support for the amendment can be found in the specification at, e.g., page 12. Thus, the rejection is obviated. Reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, are respectfully requested.

VI. CONCLUSION

Early consideration and prompt allowance of the pending claims are respectfully requested.

Respectfully submitted,

/Laura A. Donnelly/

By:_____

Laura A. Donnelly
Reg. No. 38,435

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-1729 (direct)
Dated: May 18, 2006